Government Regulations Around Opioid Prescribing

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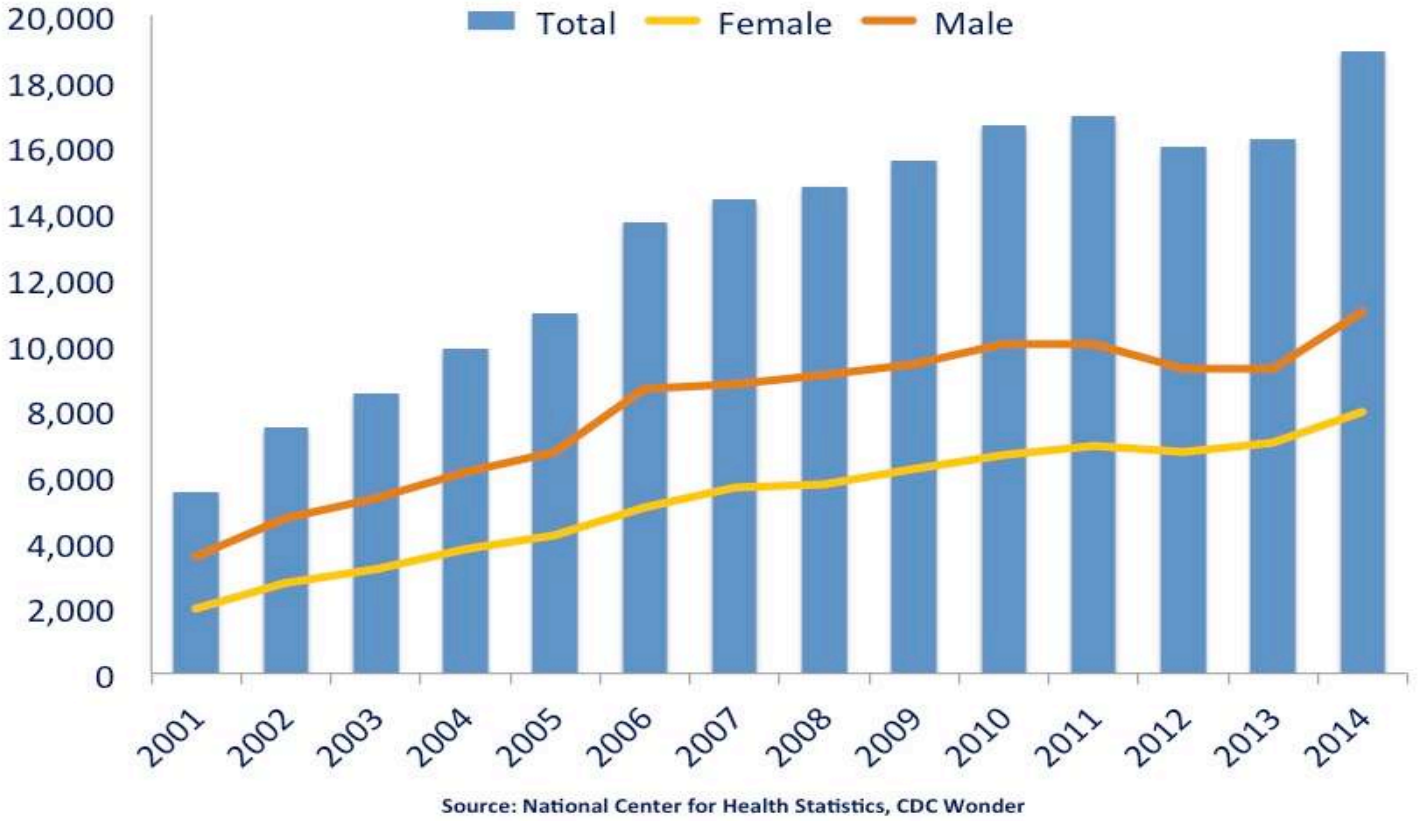
National Institute on Drug Abuse

National Overdose Deaths

Number of Deaths from Prescription Opioid Pain Relievers



Source: National Center for Health Statistics, CDC Wonder

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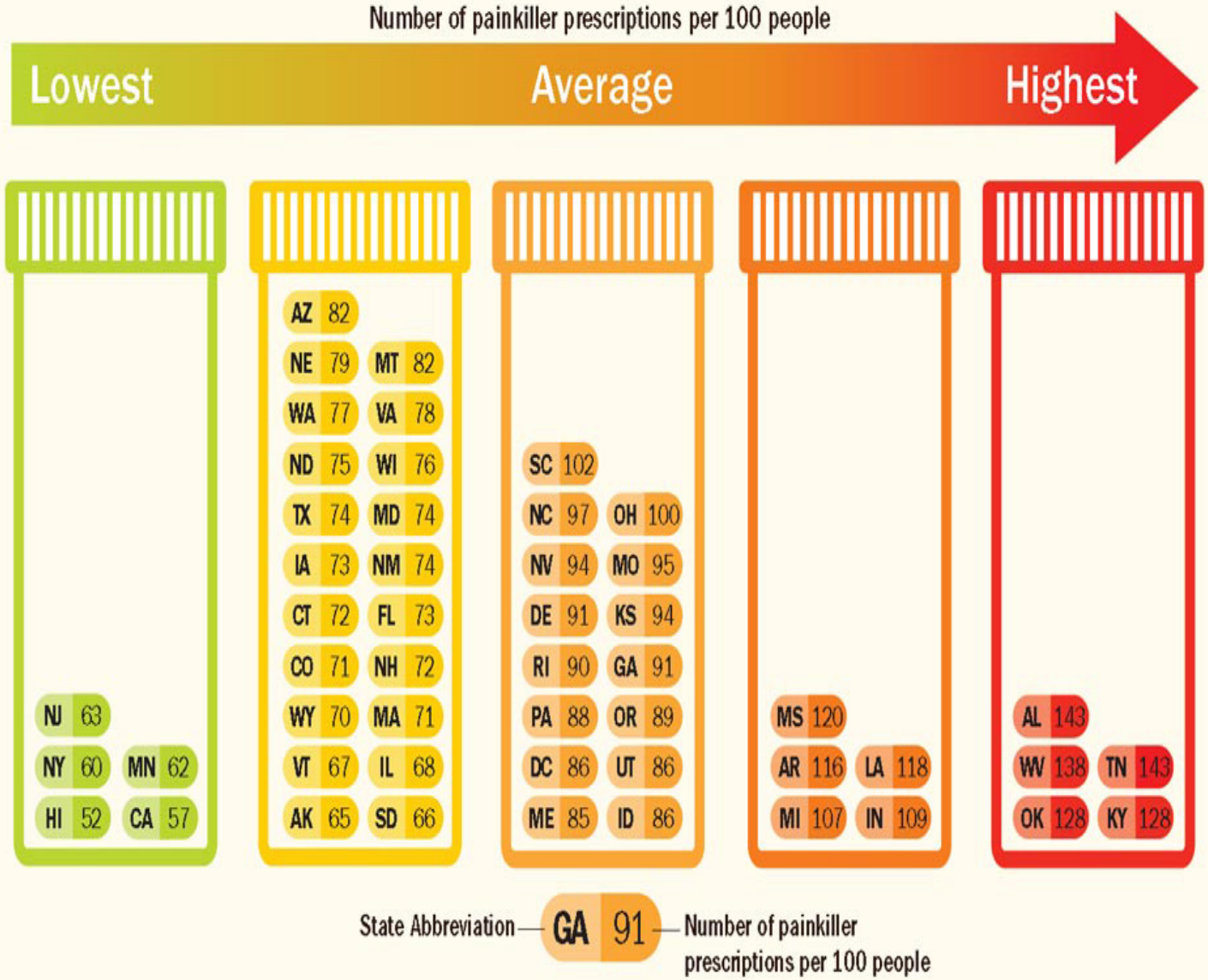
*https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates
Source: National Institute on Drug Abuse; National Institutes of Health; U.S. Department of Health and Human Services.

Health care providers in different states prescribe at different levels.

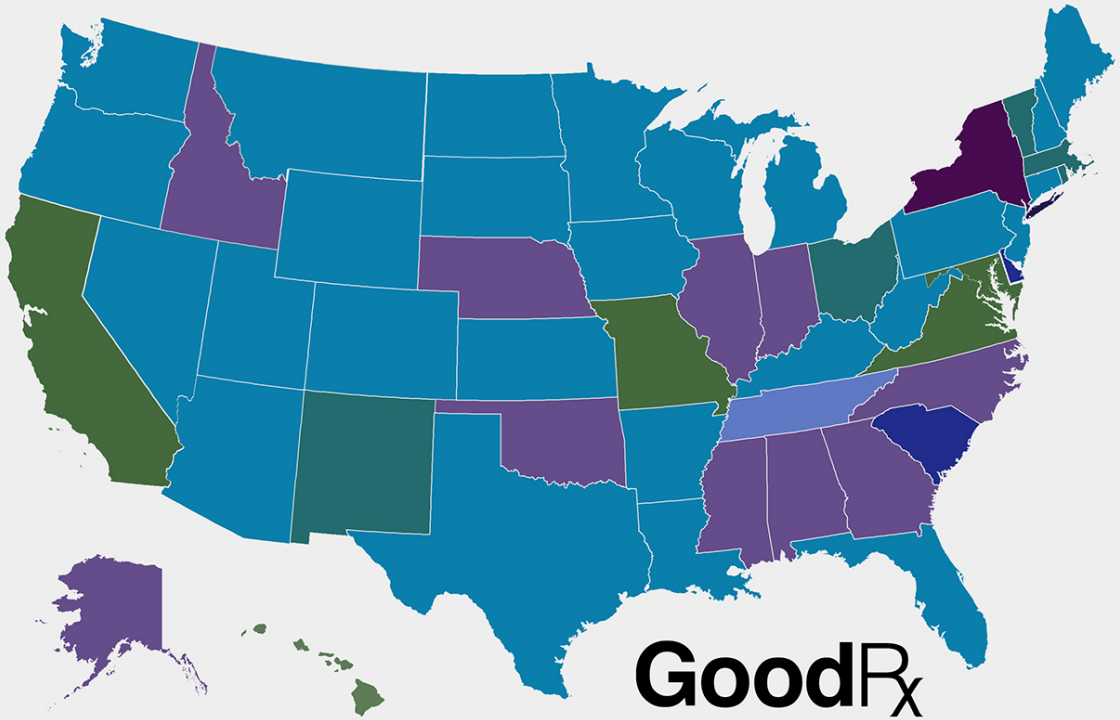


SOURCE: IMS, National Prescription Audit (NPA™), 2012.

*http://www.cdc.gov/vitalsigns/opioid-prescribing/infographic.html#infographic1
Source: CDC Vital Signs

The United States of Drugs

The most prescribed medication in each of the 50 states (2018)



Levothyroxine (Synthroid)
Hydrocodone / Acetaminophen (Norco, Vicodin)
Atorvastatin (Lipitor)
Lisinopril (Prinivil, Zestril)
Amphetamine salt combo (Adderall)
Amlodipine (Norvasc)
Buprenorphine / Naloxone (Suboxone)

Data represents volume of US prescriptions by state filled at pharmacies during 12 months ending February 2018. Data comes from several sources, including pharmacies and insurers, and provides a representative sample of nationwide US prescription drug volume. For more info, visit goodrx.com/blog

https://khn.org/news/graphic-opioid-painkiller-is-top-prescription-in-10-states/

Making a Difference: State Successes

New York
75% ↓

2012 Action:

New York required prescribers to check the state's prescription drug monitoring program before prescribing painkillers.

2013 Result:

Saw a 75% **drop in patients** who were seeing **multiple prescribers** to obtain the same drugs, which would put them at higher risk of overdose.

Florida
50% ↓

2010 Action:

Florida regulated pain clinics and stopped health care providers from dispensing prescription painkillers from their offices.

2012 Result:

Saw more than 50% **decrease in overdose deaths** from oxycodone.

Tennessee
36% ↓

2012 Action:

Tennessee required prescribers to check the state's prescription drug monitoring program before prescribing painkillers.

2013 Result:

Saw a 36% **drop in patients** who were seeing **multiple prescribers** to obtain the same drugs, which would put them at higher risk of overdose.

3

SOURCES: NY, TN: PDMP Center of Excellence at Brandeis University, 2014. FL: Vital Signs Morbidity and Mortality Weekly Report, July 1, 2014.

*http://www.cdc.gov/vitalsigns/opioid-prescribing/infographic.html#infographic1
Source: CDC Vital Signs

ILLINOIS DRUG POISONING DEATHS 2013-2015:

- 3,614 were due to opioids
- 2,113 were due to heroin
- 1,344 were due to prescription opioids

- Illinois is one of 16 states in which more people die of drug overdoses than car accidents.
- According to Illinois Public Health data, Illinois has one of the higher rates of death from heroin and opioid use.

Source: CDC/statistics 2014

FEDERAL AGENCIES AND PROGRAMS THAT ADDRESS OPIOID ABUSE:

- Department of Justice (DOJ)
  - Drug Enforcement Agency (DEA)

- Department of Health and Human Services (HSS)
  - Substance Abuse and Mental Health Services Administration (SAMHSA)

- Office of National Drug Control Policy (ONDCP)

DOJ AGENCIES/PROGRAMS:

- **DEA**
  - Regulates the flow of controlled substances in the USA
  - Controlled Substances Act (CSA)
    - Requires the DEA to establish and maintain a closed system of distribution for controlled substances
    - Regulation of anyone who handles controlled substances, including exports, importers, manufacturers, distributors, health care professionals, pharmacists and researchers.

- **Comprehensive Opioid Abuse Grant Program**
  - Treatment alternatives to incarceration programs
  - Collaboration between criminal justice and substance abuse agencies
  - Training and resources for first responders to administer opioid overdose reversal drugs
  - Investigation of illicit activities related to unlawful distribution of opioids
  - Medication Assisted Treatment Programs used by criminal justice agencies
  - Prescription Drug Monitoring Programs
  - Programs to prevent and address opioid abuse by juveniles
  - Programs that utilize technology to secure containers for prescription drugs
  - Prescription drug take back programs
  - Comprehensive opioid abuse response program

HHS AGENCIES:

- **Substance Abuse and Mental Health Services Administration (SAMHSA)**
  - Lead federal agency for increasing access to behavioral health services
  - Supports community-based mental health and substance abuse treatment and preventative services
  - Two main centers of SAMHSA combatting opioid abuse
    - Center for Substance Abuse Prevention
    - Center for Substance Abuse Treatment

- **National Institute on Drug Abuse (NIDA)**
  - Lead federal agency for advancing and applying scientific research on the causes and consequences of drug abuse

- **Centers for Medicare and Medicaid Services (CMS)**
  - Finances health care services, including substance abuse treatment services

- **Health Resources and Services Administration (HRSA)**
  - Supports access to care, including substance abuse treatment services, for underserved populations

- **Centers for Disease Control and Prevention (CDC)**
  - Seeks to prevent injuries and deaths, including those caused by drug overdoses

RECENT LEGISLATION:

- CARA - Comprehensive Addiction and Recovery Act
  - Focused primarily on opioids and also addressed broader drug abuse issues.

- Century Cures Act
  - Authorized state opioid grants and included more general substance abuse provisions as part of a larger effort to address health research and treatment.

- PASS – Preventing Addiction for Susceptible Seniors Act

- COACH – Combatting Opioid Abuse for Care in Hospitals Act

- PROPER – Providing Reliable Options for Patients and Educational Resources Act

- MOST – Medicare and Opioid Safe Treatment Act

S.524 - Comprehensive Addiction and Recovery Act of 2016

114th Congress (2015-2016)

LAW Hide Overview ✖

Sponsor: Sen. Whitehouse, Sheldon [D-RI] (Introduced 02/12/2015)

Committees: Senate - Judiciary

Committee Reports: H. Rept. 114-669 (Conference Report)

Latest Action: 07/22/2016 Became Public Law No: 114-198. (TXT | PDF) (All Actions)

Roll Call Votes: There have been 16 roll call votes

Tracker:

Introduced > Passed Senate > Passed House > Resolving Differences > To President > **Became Law**

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HIGHLIGHTS FROM CARA ACT:

- **Section 107. Improving Access to Overdose Treatment**: Award grants to federally qualified health centers (FQHCs), opioid treatment programs (OTPs), or any practitioner waivered to prescribe buprenorphine to establish a naloxone co-prescription program, train health care providers on naloxone co-prescribing, purchase naloxone, offset co-payments for naloxone, or establish protocols to connect patients who have experienced an overdose with appropriate treatment.

- **Section 110. Opioid Overdose Reversal Medication Access and Education Grant Programs**: This section authorizes the HHS Secretary to make grants to states to implement strategies for pharmacists to dispense naloxone pursuant to a standing order and to develop naloxone training materials for the public.

- **Section 301. Evidence-based Prescription Opioid and Heroin Treatment and Interventions Demonstration**: This section authorizes the HHS Secretary to award grants to state substance abuse agencies, local governments, or nonprofit organizations in areas with high rates of or rapid increases in heroin or other opioid use to expand the availability of medication-assisted treatment. It authorizes $25 million for each fiscal year between 2017 and 2021.

- **Section 303. Medication-Assisted Treatment for Recovery from Addiction:** This section makes several changes to the law regarding office-based opioid addiction treatment with buprenorphine. Specifically, it:
- Expands prescribing privileges to nurse practitioners (NPs) and physician assistants (PAs) for five years (until October 1, 2021). NPs and PAs must complete 24 hours of training to be eligible for a waiver to prescribe and must be supervised by or work in collaboration with a qualifying physician if required by state law. The HHS Secretary has 18 months to issue updated regulations governing office-based opioid addiction treatment to include NPs and PAs.
    - Nurse practice laws and regulations are specific to each state. The American Association of Nurse Practitioners (AANP) has created an interactive map to provide licensure and regulatory requirements, as well as practice environment details, for all 50 states and the U.S. Territories. AANP also has a list of state practice laws and regulations categorized by type.

Congress.com/bill

HIGHLIGHTS FROM CARA ACT:

- Gives the HHS Secretary the authority to exclude from the patient limit those patients to whom medications are directly administered.
- Directs the HHS Secretary to review the provision of opioid addiction treatment services in the U.S. and submit a report to Congress, including an assessment of whether there is need to change the patient limit, every three years.
- Allows states to lower the patient limit and allows states to require practitioners to comply with additional practice setting, education or reporting requirements. States may not lower the patient limit below 30.

- **Section 501. Improving Treatment for Pregnant and Postpartum Women**: This section reauthorizes a grant program for residential opioid addiction treatment of pregnant and postpartum women and their children and creates a pilot program for state substance abuse agencies to address identified gaps in the continuum of care, including non-residential treatment services.

- **Section 601. State Demonstration Grants for Comprehensive Opioid Abuse Response:** This section authorizes the HHS Secretary to award grants to states to establish a response plan to the opioid epidemic. The plan may include:
  - Education efforts related to opioid use, treatment and addiction recovery, including education of medical students, residents, physicians and other controlled substances prescribers
  - Establishing, maintaining or improving a prescription drug monitoring program (PDMP)
  - Expanding the availability of prescription opioid addiction treatment
  - Developing, implementing and expanding efforts to prevent opioid overdose deaths
  - Advancing education and awareness of the public regarding the dangers of opioid misuse, safe medication disposal and detection of early signs of opioid addiction

S.483 - Ensuring Patient Access and Effective Drug Enforcement Act of 2016

114th Congress (2015-2016)

LAW Hide Overview ✖

Sponsor: Sen. Hatch, Orrin G. [R-UT] (Introduced 02/12/2015)

Committees: Senate - Judiciary

Latest Action: 04/19/2016 Became Public Law No: 114-145. (TXT | PDF) (All Actions)

Tracker:

Introduced > Passed Senate > Passed House > To President > **Became Law**

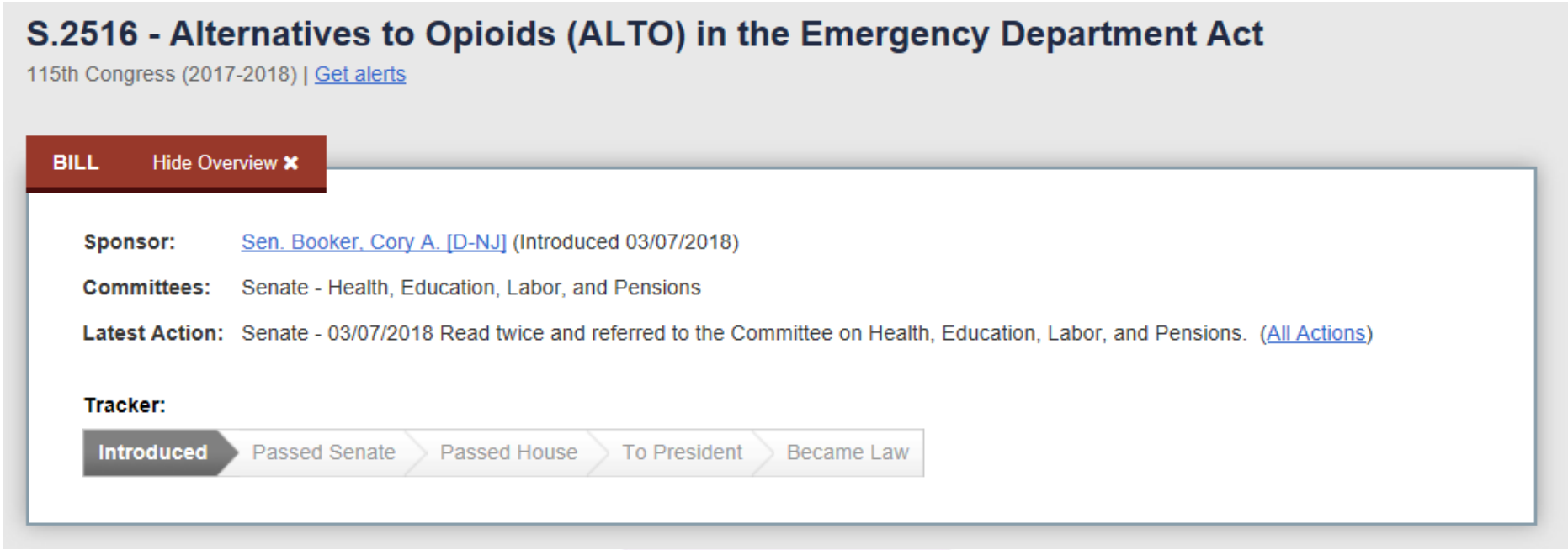
ENSURING PATIENT ACCESS AND EFFECTIVE DRUG ENFORCEMENT ACT OF 2016 HIGHLIGHTS:

- (Sec. 2) This bill amends the Controlled Substances Act to define phrases related to the Drug Enforcement Administration's (DEA's) authority to register manufacturers, distributors, and dispensers of controlled substances.
    - Currently, the DEA registers a controlled substances manufacturer, distributor, or dispenser if it is in the public interest after considering certain factors, including factors relevant to and consistent with the public health and safety. This bill defines "factors as may be relevant to and consistent with the public health and safety" to mean factors relevant to and consistent with the specified purposes of the Controlled Substances Act.
    - Additionally, current law allows the DEA to immediately suspend a registration to prevent imminent danger to the public health and safety. This bill defines "imminent danger to the public health and safety" to mean an immediate threat of death, serious bodily harm, or abuse of a controlled substance due to a registrant's failure to maintain effective controls against diversion.
    - The bill revises and expands the required elements of an order to show cause issued by the DEA before it denies, revokes, or suspends a registration for a Controlled Substances Act violation. An order to show cause must specifically state the legal basis for the action and notify the registrant of the opportunity to submit a corrective action plan.

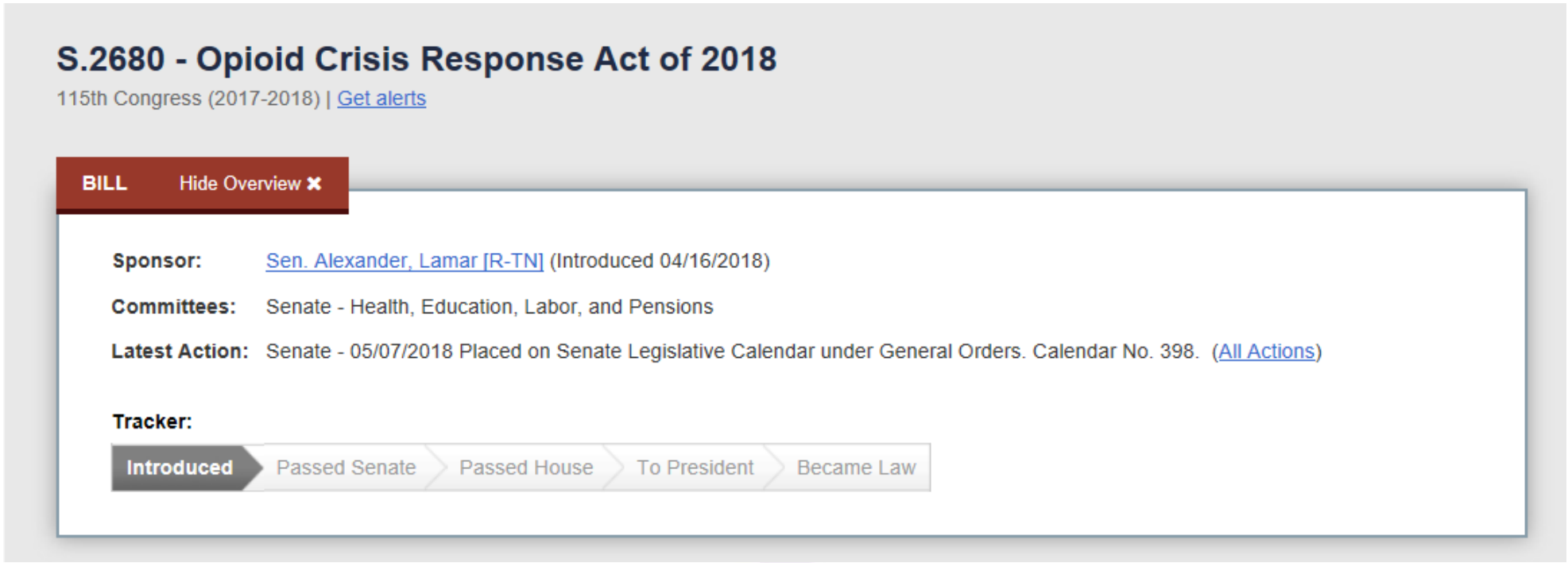
- (Sec. 3) The Food and Drug Administration, the Substance Abuse and Mental Health Services Administration, the Agency for Research and Quality, and the Centers for Disease Control and Prevention, in coordination with the DEA, must report to Congress on:
    - obstacles to legitimate patient access to controlled substances;
    - diversion of controlled substances;
    - how collaboration between law enforcement agencies and the pharmaceutical industry can benefit patients and prevent diversion and abuse of controlled substances;
    - the availability of and gaps in medical education, training opportunities, and comprehensive clinical guidance for pain management and opioid prescribing;
    - enhancements to prescription drug monitoring programs; and
    - improvements to prescription opioid reporting requirements.

- This bill amends the Controlled Substances Act to prohibit the Drug Enforcement Administration from registering, or renewing the registration of, a practitioner who is licensed to prescribe opioids in schedule II, III, or IV unless the practitioner agrees to limit an opioid prescription for the initial treatment of acute pain to the lesser of a seven-day supply (no refill) or an opioid prescription limit established under state law.

- An opioid that is approved and prescribed for the treatment of addiction is not subject to the limit.



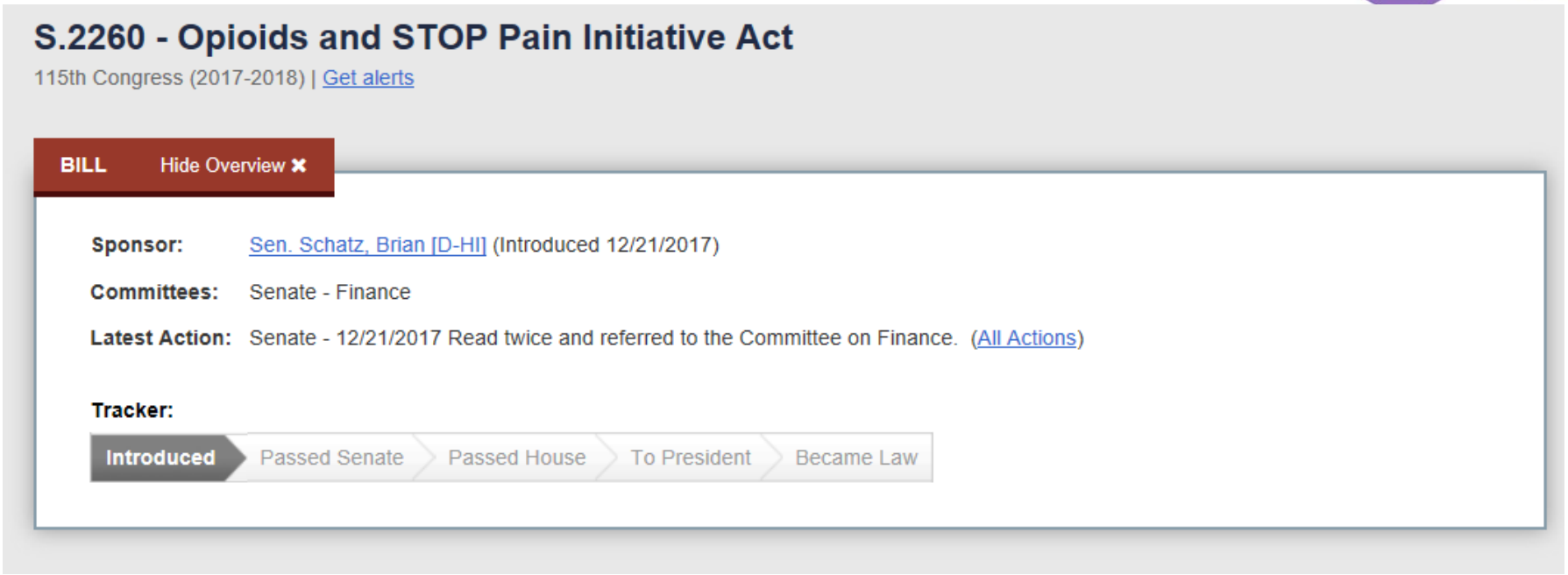
- Appropriates $10 million annually from FYs 2019 to 2021 for a 3 year demonstration program.
  - Alternative pain management protocols and treatments
- Appropriately limit the use of opioids in emergency departments



Includes provisions to:

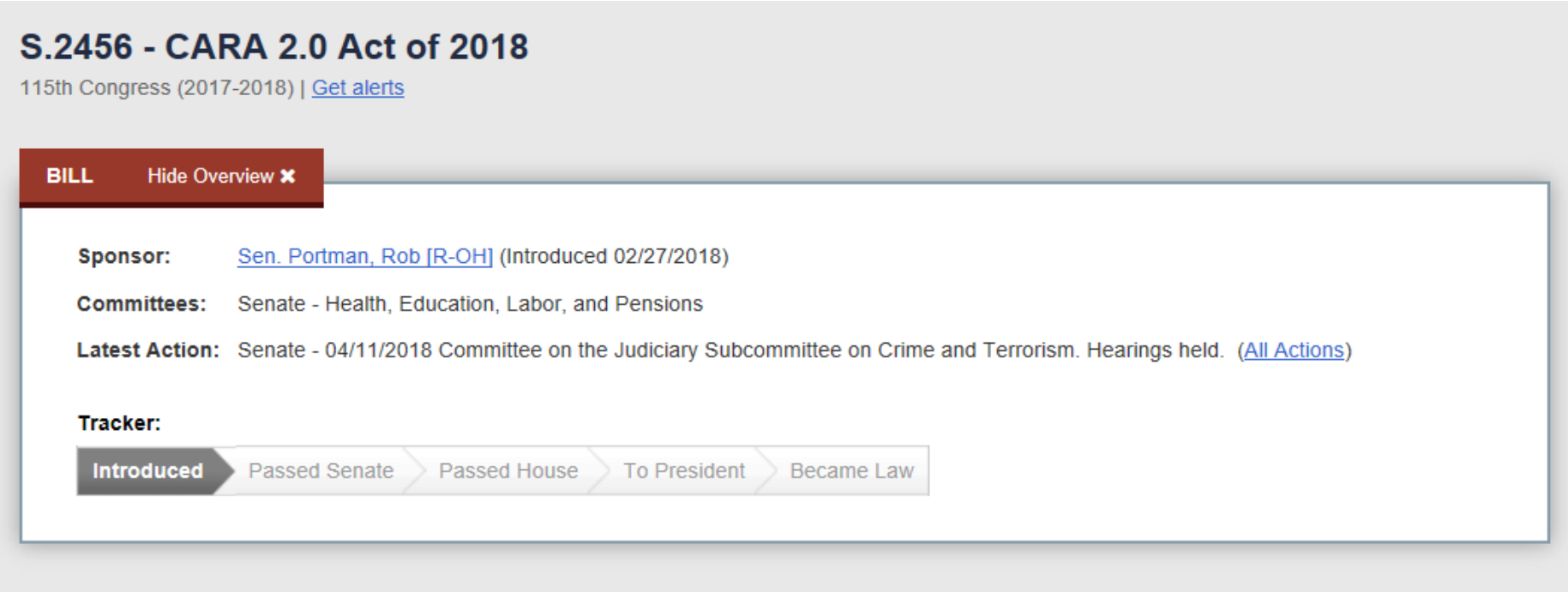
- Clarify FDA authority to require packaging options for opioids to support a set treatment duration, eg, blisterpacks for patients who only need 3- or 7-day supply

- Study Prescribing Limits
  - Impact of federal and state laws that limit the length, quantity, or dosage of opioid prescriptions



- Appropriates $5 billion to support NIH research authorized under CARA 1.0 to:
  - Understand Pain
  - Discover New Chronic Pain Therapies
  - Develop Alternatives to Opioid Pain Treatments

- NIH will develop a new Pain Therapy Screening Program, to support the development of new models for pain disorders and the application of these models in drug, device or other therapy screening.



- Limits initial opioid prescriptions for acute pain to 3 days.
  - Chronic pain, cancer pain, end of life, and other palliative care treatments are generally exempt from the limit.

- Requiring prescribers to check and pharmacists to report to state PDMPs upon initial prescription of a schedule II, III, or IV controlled substance.

- Increased civil and criminal penalties for opioids manufacturers who fail to report suspicious orders or fail to maintain effective controls against diversion.

S.2819 - A bill to require the Secretary of Veterans Affairs to report on opioid prescribing rates of physicians of the Veterans Health Administration and to conduct pain management training for those physicians with the highest rates of opioid prescribing.

115th Congress (2017-2018) | Get alerts

BILL Hide Overview ✖

Sponsor: Sen. Inhofe, James M. [R-OK] (Introduced 05/10/2018)

Committees: Senate - Veterans' Affairs

Latest Action: Senate - 05/10/2018 Read twice and referred to the Committee on Veterans' Affairs. (All Actions)

Tracker:

Introduced | Passed Senate | Passed House | To President | Became Law

More on This Bill

CBO Cost Estimates [0]

Subject — Policy Area:

Armed Forces and National Security

View subjects »

DOSE AND DURATION LIMITS:

- >130 bills considered between 2016 – 2017

- April 2018
  - 19 states passed legislation limiting opioid prescriptions
    - To prevent dependence
    - To limit leftover supply at risk of diversion

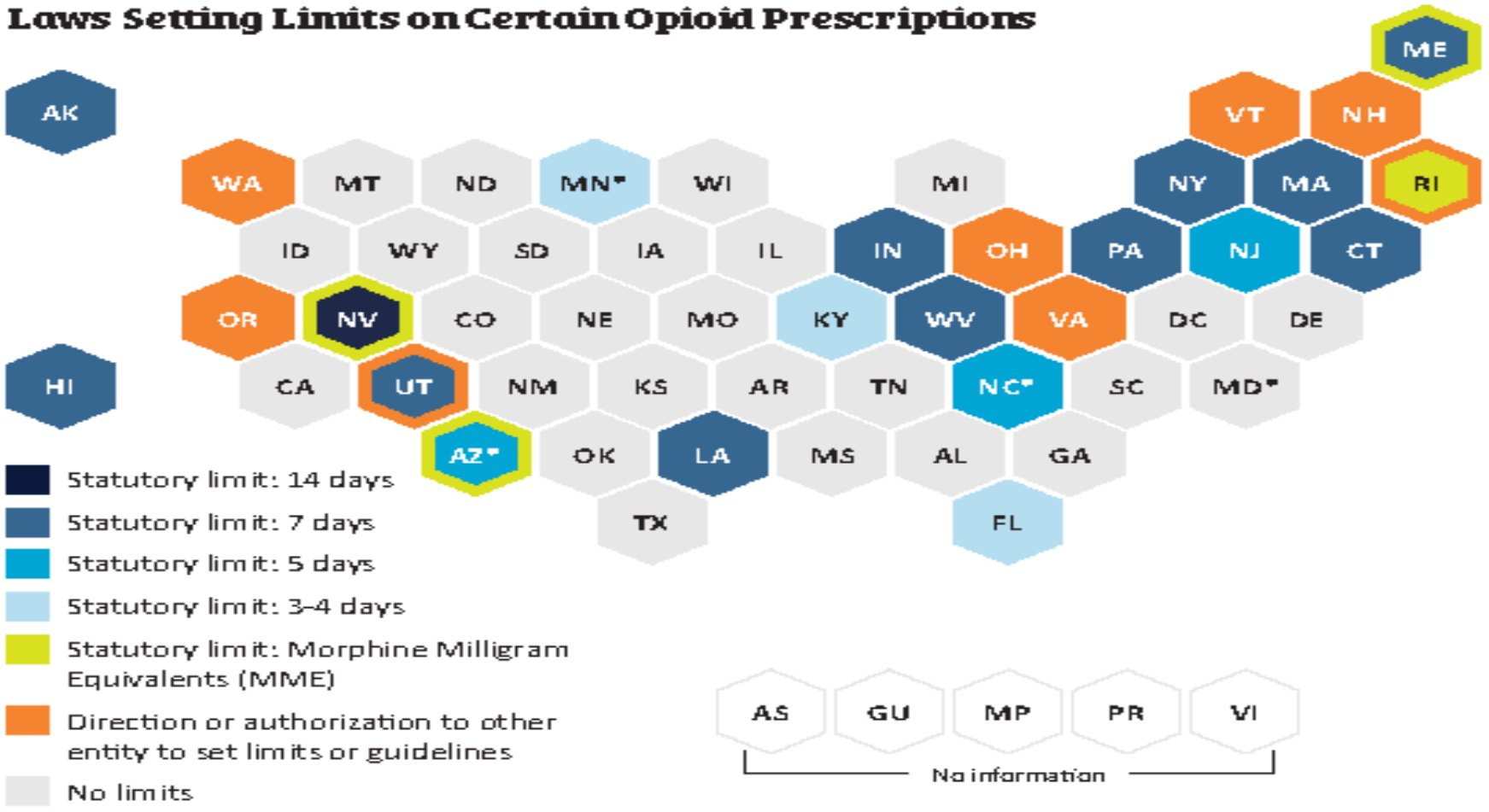
- Most limit duration
  - Ranging between 3 to 14 day supplies
  - With 7 day supply being the most common

- Most states set exceptions
  - Most commonly for chronic pain, cancer, palliative and hospice based care

BASIC RECOMMENDATIONS:

- 4 – 9 days for general surgery
- 4 – 13 days for women’s health procedures
- 6 – 15 days for musculoskeletal procedures

Laws Setting Limits on Certain Opioid Prescriptions



* Note: The map displays the state's primary opioid prescription limit and does include additional limits on certain providers or in certain settings. Arizona allows prescriptions up to 14 days following surgical procedures and North Carolina allows up to 7 days for post-operative relief. Maryland requires the "lowest effective dose." Minnesota's limit is for acute dental or ophthalmic pain. The map also does not reflect limits for minors that exist in at least eight states.

Source: NCSL, StateNet

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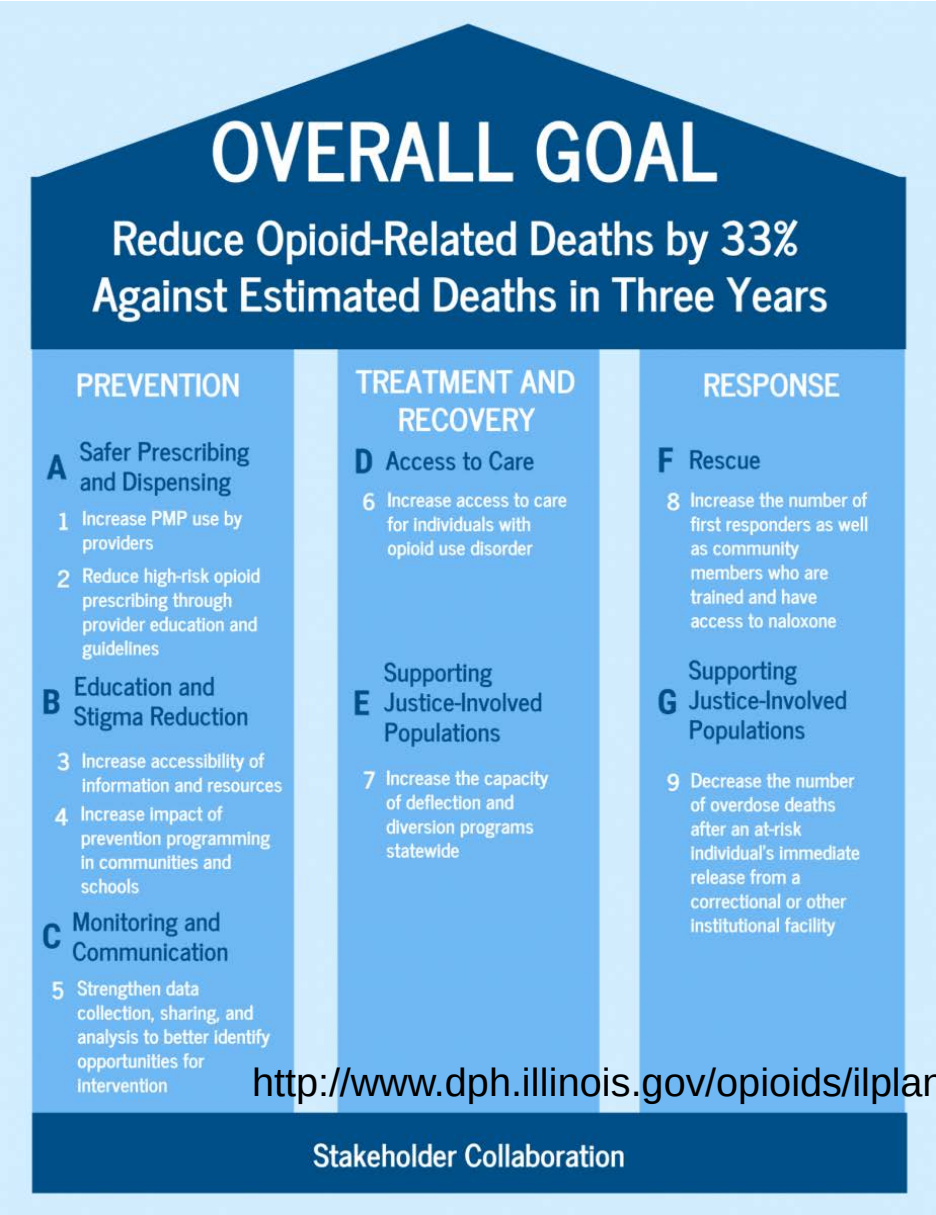
http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx

ILLINOIS OPIOID ACTION PLAN:

- This plan focuses on efforts falling into three pillars, which are:
  - Prevention
    - preventing the further spread of the opioid crisis
  - Treatment and Recovery:
    - providing evidence-based treatment and recovery services to Illinois residents with opioid use disorder (OUD)
  - Response:
    - averting overdose deaths



http://www.dph.illinois.gov/opioids/ilplan

IL PDMP:

Prescription Monitoring:

- Prescription monitoring programs are state-run electronic databases that collect and distribute data about the prescription and dispensation of controlled substances.
- State prescription monitoring programs have been shown to lead to reductions in doctor “shopping” behavior, opioid prescribing, and overdose death rates.

Illinois Prescription Monitoring Program (ILPMP):

- ILPMP collects information on controlled substance prescriptions (Schedules II, III, IV and V). These data are required to be reported on a daily basis by all retail pharmacies dispensing prescriptions in Illinois.
- Under Public Act 100-0564 (2017), all Illinois prescribers (with certain exceptions) must document an attempt to check the ILPMP when providing an initial prescription for Schedule II narcotics (including opioids).
- ILPMP data assist health care providers assess prescribing practices, inform efforts to reduce high-risk opioid prescribing, and help prevent misuse of controlled substances and medical error.

DRUG ADDICTION TREATMENT ACT OF 2000 (DATA 2000)

- The legislation waives the requirement for obtaining a separate Drug Enforcement Administration (DEA) registration as a Narcotic Treatment Program (NTP) for qualified physicians administering, dispensing, and prescribing these specific FDA approved controlled substances.

- Physicians registered with the DEA as practitioners who apply and are qualified pursuant to DATA are issued a waiver (DWP) and will be authorized to conduct maintenance and detoxification treatment using specifically approved schedule III, IV, or V narcotic medications.

- Qualified physicians are permitted to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications (medications that have a lower risk for abuse, like buprenorphine) in settings other than an opioid treatment program (OTP) such as a methadone clinic.

DATA OF 2000

- In order to prescribe or dispense buprenorphine, physicians must qualify for a physician waiver, which includes completing eight hours of required training, and applying for a physician waiver.

- A “qualifying physician” is specifically defined in DATA 2000 as one who is:
  - Licensed under state law (excluding physician assistants or nurse practitioners)
  - Registered with the Drug Enforcement Administration (DEA) to dispense controlled substances
  - Required to treat no more than 30 patients at a time within the first year
  - Qualified by training and/or certification
  - Also, in order to maintain a waiver, a physician must be capable of referring patients to counseling and other services.

DATA OF 2000

- Physicians must apply to SAMHSA to provide buprenorphine treatment beyond the 30-patient limit for up to 100 patients with opioid dependency.

- Physicians who have prescribed buprenorphine to 100 patients for at least one year can now apply to increase their patient limits to 275 under the Office of National Drug Control Policy Reauthorization Act of 2006.

ILLINOIS PUBLIC ACT 099-0480 (HB1):

- Illinois Public Act 099-0480 (HB0001) passed and became effective September 9, 2015.

- Enables non-medical persons to administer Naloxone to persons experiencing an opioid overdose.

- Requires emergency responders such as EMS, firefighters, law enforcement, and pharmacists to be trained in administering Naloxone through its various forms of administration.

- Updates previous laws and Allows Department of Human Services- DASA to further implement the Drug Overdose Prevention Program (DOPP) to encourage, establish and authorize programs to become enrolled to distribute naloxone statewide.

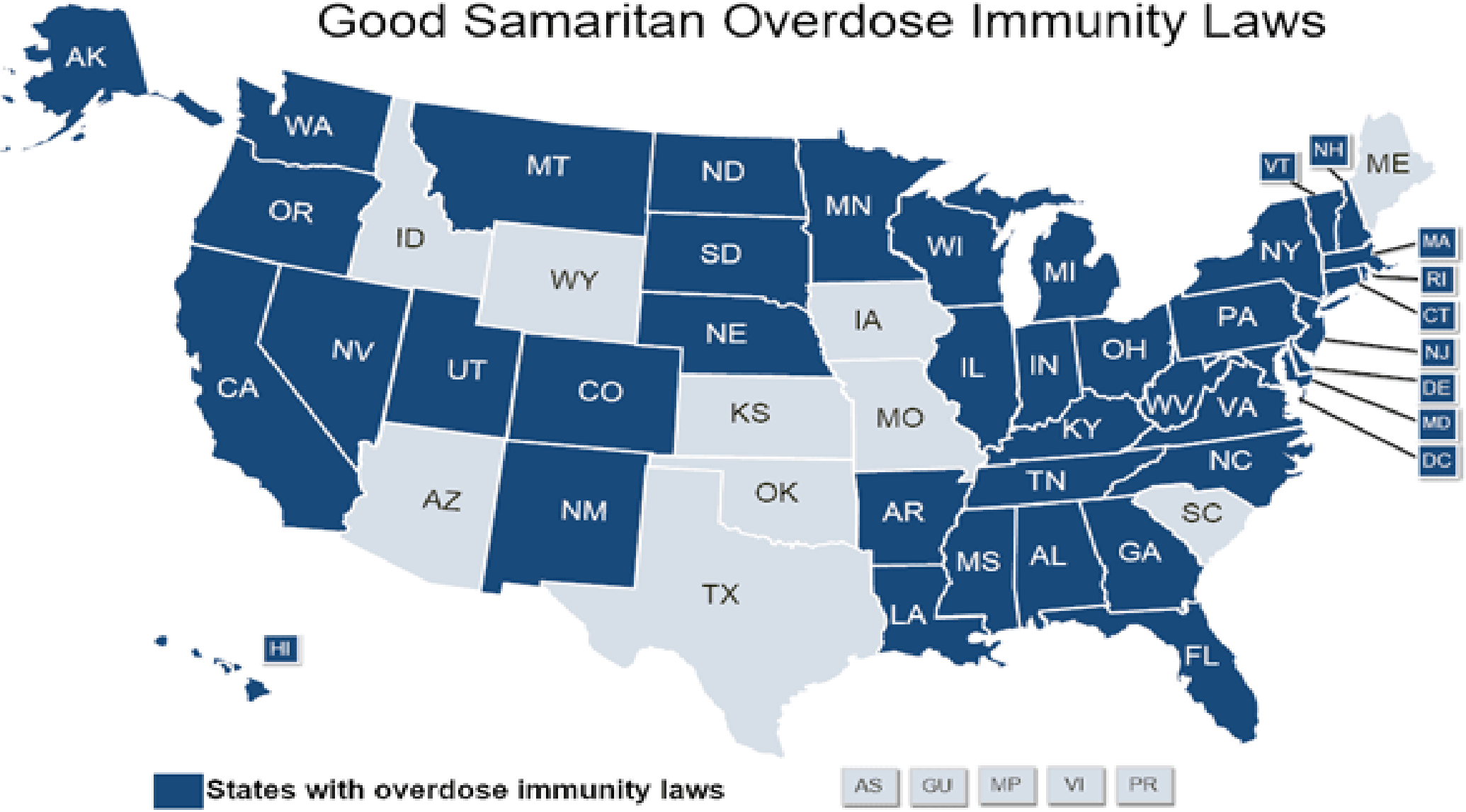
http://www.dhs.state.il.us/page.aspx?item=58142

- To encourage people to seek out medical attention for an overdose or for follow-up care after naloxone has been administered, 40 states and the District of Columbia have enacted some form of a Good Samaritan or 911 drug immunity law.

- These laws generally provide immunity from arrest, charge or prosecution for certain controlled substance possession and paraphernalia offenses when a person who is either experiencing an opiate-related overdose or observing one calls 911 for assistance or seeks medical attention.

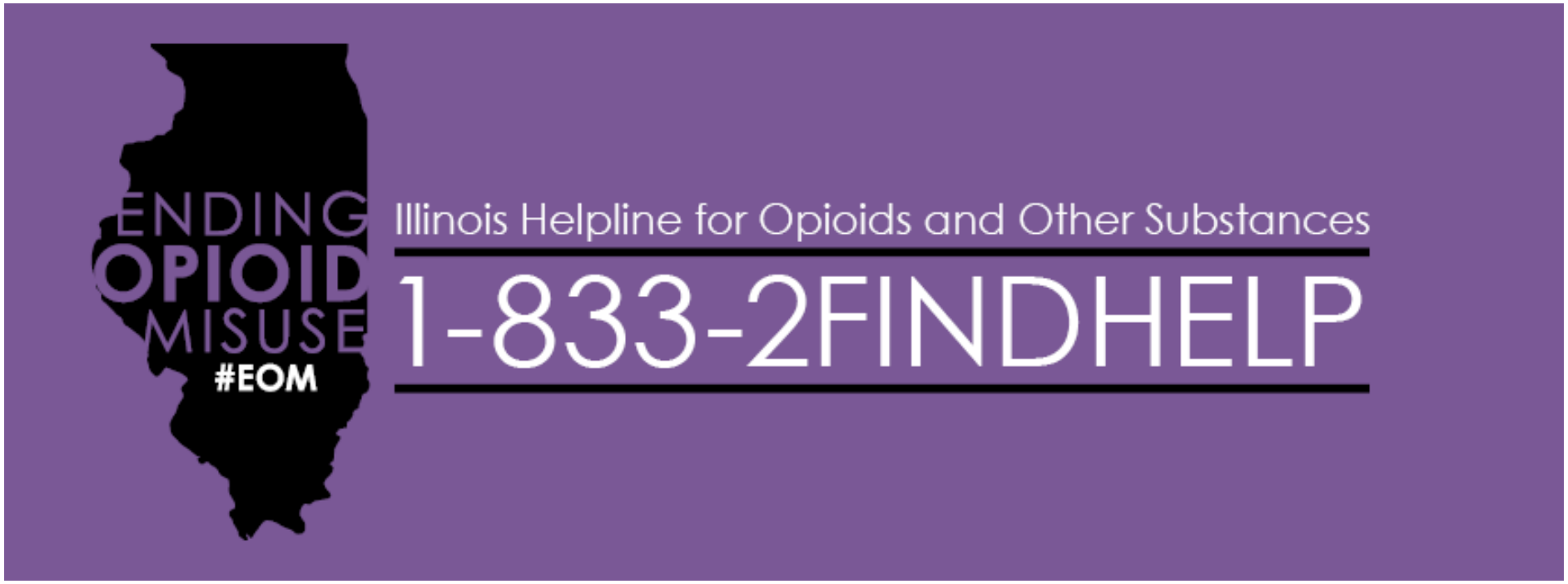
- State laws are also increasingly providing immunity from violations of pretrial, probation or parole conditions and violations of protection or restraining orders.

Good Samaritan Overdose Immunity Laws



http://www.ncsl.org/research/civil-and-criminal-justice/drug-overdose-immunity-good-samaritan-laws.aspx

ILLINOIS OPIOID HELPLINE



DRUG TAKEBACK PROGRAMS

National Take Back Day Results

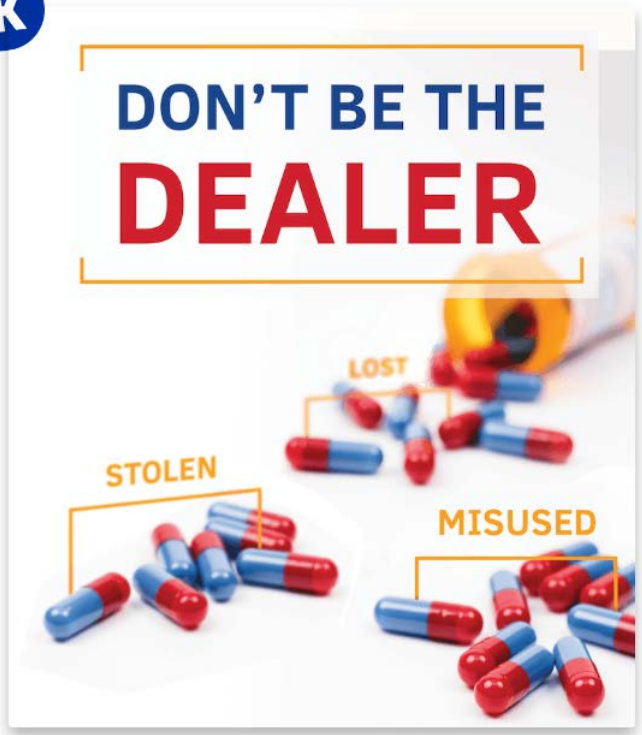
April 2018 | **October** 2017 | **April** 2017 | **October** 2016 | **May** 2016

Results: April 2018 15th National Take Back

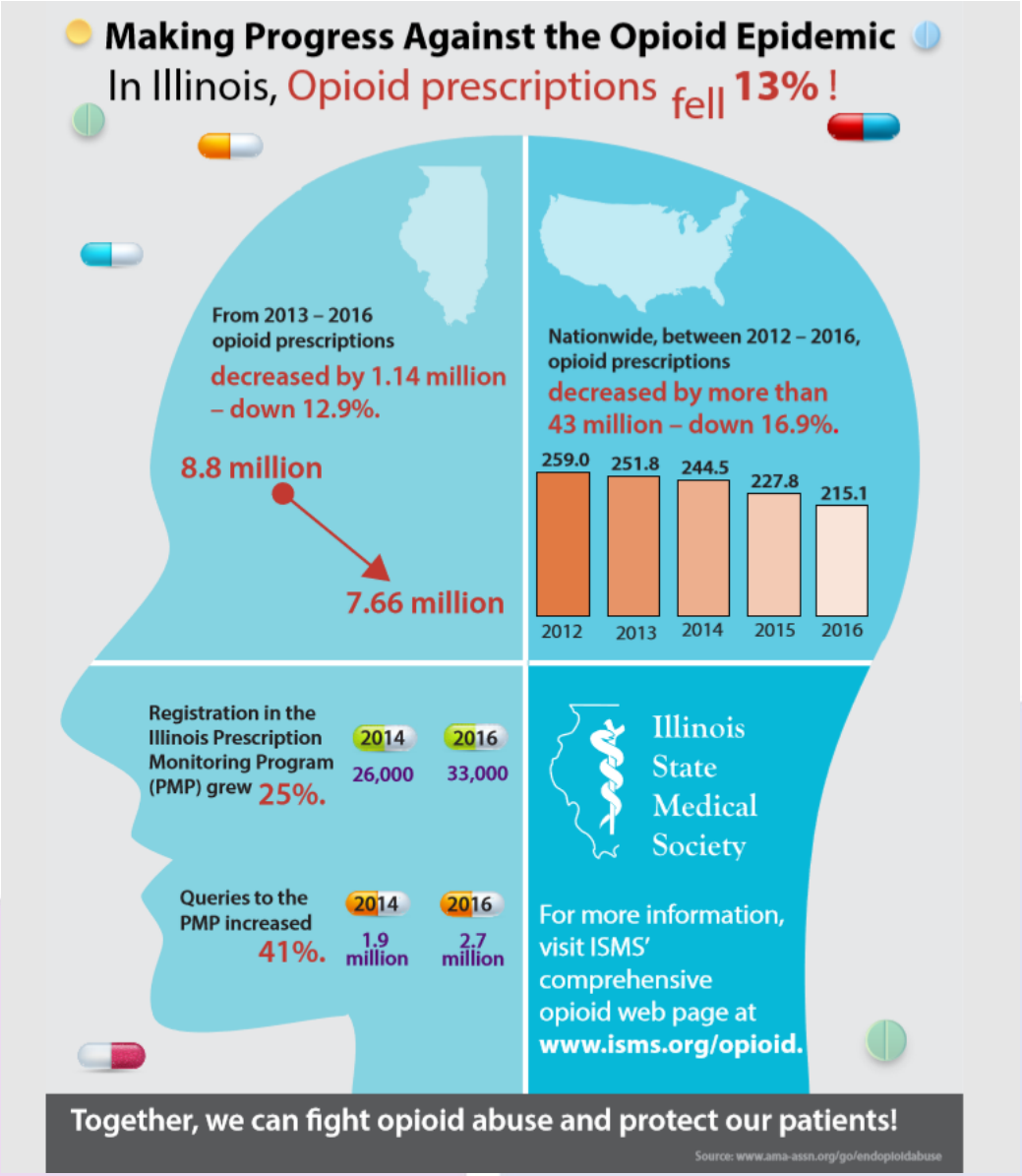
- Total Law Enforcement Participation: **4,683**
- Total Collection Sites: **5,842**
- Total Weight Collected: **949,046 lbs. (474.5 Tons)**

DEA NATIONAL Rx TAKEBACK

Too often, unused prescription drugs find their way into the wrong hands. That's dangerous and often tragic. That's why it was great to see thousands of folks from across the country clean out their medicine cabinets and turn in - safely and anonymously - a record amount of prescription drugs.



SEEING IMPROVEMENTS



https://www.isms.org/Resources/For_Physicians/Medication/17-2693-R_ISMS_Opiod_infographic/

FDA APPROVES FIRST MEDICATION SPECIFICALLY FOR OPIOID WITHDRAWAL

- May 16: Food and Drug Administration (FDA) approved lofexidine hydrochloride (brand name Lucemyra) for the treatment of the physical symptoms associated with opioid withdrawal in adults.
- Lofexidine is a selective alpha 2-adrenergic receptor agonist and was initially developed as a hypertension medication.
- Previously, to treat a patient's symptoms of opioid withdrawal, physicians were limited to prescribing clonidine (another hypertensive medication) off-label.
- Lofexidine now provides the benefits of clonidine in an approved formulation.
- Lofexidine is a more specific alpha-2 agonist than clonidine, so theoretically should have less propensity to lower blood pressure and heart rate at therapeutic doses.
- The FDA also noted that this treatment is approved for use for a maximum of 14 days.

https://psychnews.psychiatryonline.org/doi/full/10.1176/appi.pn.2018.pp6a1

HELPFUL RESOURCES:

US Health and Human Services: https://www.hhs.gov/opioids/

Department of Justice: https://www.justice.gov/opioidawareness

Illinois Controlled Substances Act: http://www.ilga.gov/legislation/ilcs/ilcs5.asp?ActID=1941&ChapterID=53

National Institute on Drug Abuse: https://www.drugabuse.gov/drugs-abuse/opioids

Illinois Opioid Action Plan: http://dph.illinois.gov/opioid/docs

DEA National RXTake Back Day: takebackday.dea.gov/.

SIU Best Practices in Rural Opioid Prescribing: https://www.siumed.edu/psych/best-practices-rural-opioid-prescribing.html